UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,343	10/15/2001	Margaret K. Hostetter	110.00280103	4625

26813 7590 03/21/2003

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER	
KAUFMAN, CLAIRE M	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,343	HOSTETTER ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29,32-37 and 40-48* is/are rejected.

7)☒ Claim(s) *30,31,38 and 39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The preliminary amendment filed 10/15/01 has been entered.

Claim Interpretation

Claims, such as claim 32, wherein the antibody is to a peptide comprising a specific sequence, are interpreted to mean that the antibody binds the specific sequence instead of the unspecified sequence it may be comprised within.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 32, 33, 37, 42 and dependent claims 34, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 is indefinite because "has" and "having" are interpreted as open-language to meaning "comprising. Therefor, the claim is drawn to an antibody to a peptide which comprises an amino acid sequence comprising SEQ ID NO:3. Since "peptide" and "protein" (claim 28) are apparently used distinctly, it is unclear how big the "peptide" of claim 32 can be, *i.e.*, can it be as big as the protein of SEQ ID NO:2? This rejection could be obviated by substituting the word "of" for "having". However, see the "Claim Interpretation" above.

Claims 29, 33, 37 and 42 are indefinite for reciting "or combination thereof". It is unclear how an antibody can be a combination of a monoclonal and a polyclonal antibody.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-44 and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO:1, the sequence of the nucleic acid encoding the *C. albicans* integrin-like polypeptide having the sequence of SEQ ID NO:2. Antibodies to the polypeptide of SEQ ID NO:2, to a polypeptide encoded by the polynucleotide of SEQ ID NO:1 or to the fragment of SEQ ID NO:2 set forth in SEQ ID NO:4-8 are also within the purview of the specification. Note that while it is unpredictable if antibodies to SEQ ID NO:4, 7 and 8 would block *C. albicans* peptide or polypeptide (see p. 23 of the specification), if they did not they would inoperative embodiments not affecting what is sufficiently described. What the specification does not disclose are antibodies to sequences other than the disclosed SEQ ID NO:2 or fragments thereof. For example, there is no disclosure of a *C. albicans* peptide with integrin-like motifs that does not have the sequence of SEQ ID NO:2 or a fragment thereof so that one cannot envision an antibody that binds to an undisclosed sequence.

An antibody to SEQ ID NO:2 or fragments thereof comprising SEQ ID NO:3-8 meet the written description and enablement provision of 35 USC 112, first paragraph. However, the claims are directed to or encompass an antibody to a *C. albicans* peptide with integrin-like motifs (A) not having the sequence of SEQ ID NO:2 or a fragment thereof which comprising SEQ ID NO:3-8 *and* not having a specified sequence though obtained from a specific developmental stage, wherein the antibody blocks binding of the peptide to epithelial cells (claim 40), or (B) encoded by a polynucleotide that hybridizes under fairly high stringent conditions to SEQ ID NO:1 (claim 40) and has certain general structural features (claim 41). Note that the antibody must be to a peptide that occurs in nature, a "*C. albicans* peptide", so that the antibody is to a very specific set of peptides/polypeptides, only a very limited number of which are disclosed. None of the antibodies to undisclosed sequences meets the written description provision of 35 USC 112, first paragraph. One cannot readily envision what the undisclosed naturally occurring sequences are.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an antibody to one of the disclosed sequences, but not the full breadth of the claim meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28, 29, 32, 33, 36, 37, 40-42 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Meinke et al. (Ped. Res., 35(4/2):187A, #1106, April 1994).

Meinke et al. monoclonal antibodies for αM and αX that bind *C. albicans* and one of which recognizes a 165±15 kD integrin-like protein on Western blot. This protein appears to be

the integrin-like protein of SEQ ID NO:2 disclosed in the instant specification because: 1)they are both integrin-like proteins, 2) are encoded by DNA from C. albicans, but not in C. tropicalis or S. cervisiae, 3) have the same approximate molecular weight--165+15 kD compared to 180-190 kD of the disclosed protein, p. 6, line 1 of the specification, 4) mediate adhesion to human epithelial cells (see p. 5, lines 24-26 of the specification), 5) were originally isolated as a 3.5 kb EcoRI genomic fragment and subsequently as an approximately 11 kb fragment (see p. 17, lines 17-29), 6) are encoded by approximately 5000 nucleotides (i.e., a 4990 bp open reading frame disclosed on p. 18, line 11, of the specification; and a 5-6 kb mRNA of prior art), and 7) hybridize to an oligonucleotide containing the KVGFFK consensus sequence (p. 17, line 19, of specification. It reasonably appears, absent evidence to the contrary, that the DNA of Meinke is the same disclosed as having SEQ ID NO:1 in the instant application, encoding the integrin-like protein of SEQ ID NO:2. Therefore, antibodies that bind to the integrin-like protein of Meinke anticipate the antibodies of the claims rejected here.

Note that because claim such as 32 and 36 use open language, they read on an antibody that binds the full length protein. Also, it is not necessary for the reference to be enabling for making the protein since claims are to an antibody which is explicitly taught and publicly available.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,146,824 discloses in Figure 6 (col. 13, lines 58-61) that anti-thrrombin antibodies that specifically recognize the RGD-exposed site do not bind the RGD motif present in other proteins such as fibronectin, fibrinogen or vitronectin. Therefore, this references teaches away from making an antibody to an RGD in a context other than the *C. albincans* integrin-like peptide that would reasonably be expected to cross-react with or anticipated the claimed antibodies.

Conclusion

Claims 29, 32-35, 37 and would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 30, 31, 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

March 20, 2003